

REMARKS

I. Status of the claims

Claims 1, 2, 5, and 14 are amended.

Claims 1-11 and 14-17 are currently pending.

II. Support and rationale for the amendment

Support for the amendment is found at page 6, lines 24-27 of the specification. The amendment is made solely for procedural reasons (*i.e.*, in support of an argument for Unity of Invention). Accordingly, the amendment is not made for reasons relating to the patentability of the claims and is not believed to narrow the scope of the claims. A complete copy of the pending claims, including marked up versions of the amended claims is attached hereto.

III. Specific response to Restriction

In issuing the instant restriction requirement, the Examiner has restricted to the claims to one of IV groups, namely:

- Group I: claims 1-3 and 5-11 drawn to detection/quantification of CNS damage based on analysis of cerebrospinal fluid.
- Group II: Claims 1, 2 and 4-11 drawn to detection/quantification of CNS damage based on analysis of ~~cerebrospinal fluid~~ ^{blood derivatives}.
- Group III: Claims 14-16 drawn to a kit comprising a tool for the detection of tau wherein the kit comprises a monoclonal antibody, a secondary antibody, a marker, and appropriate buffer solutions.
- Group IV: Claim 17 drawn to a method for screen or monitor the effect of compounds which prevent or treat CNS damage.

In support of the Restriction Requirement, the Examiner alleged that the instantly pending claims do not define a "special technical feature which constitute an contribution over the prior art. The Examiner specifically alleges that claims 1-3, 16, and 17 are anticipated by WO 94/13795. The restriction goes on to assert that:

[t]his patent application discloses that the invention aims at providing a process (method) for the detection or diagnosis in vitro of brain disease involving tau protein. This patent application also discloses that Alzheimer's disease (AD), a form of CNS damage in an individual, is characterized neuropathologically by the presence of neuritic (senile) plaques (holes or space-occupying lesions) and neurofibrillary tangles (NFT). Therefore, claims 1, 2, 3, 16, and 17 lack a special technical feature and cannot share one with the other claims.

Applicant responds as follows.

Claims 1, 2, and 14 are now amended to replace the limitation "space-occupying lesions" with the limitations "*benign primary brain tumors, malignant primary brain tumors, brain metastasis, hydrocephalus, subdural haematoma, and/or parasite derived cysts.*"

This amendment, clarifies the fact that CNS damage resulting from Alzheimer's disease (AD) is not encompassed by the types of CNS damage listed in the pending claims. Since the cited art does not teach or discuss any type of CNS damage other than that caused by AD, it does not anticipate any of the current claims. Furthermore, WO 94/13795 does not teach or suggest a relationship between tau levels and the types of CNS damage recited in the currently pending claims and therefore does ^{not} anticipate the pending claims.

Applicant notes that PCT Rule 13 recites, *inter alia*:

Where a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

PCT Rule 13.2. Applicant asserts that, as amended the currently pending claims meet the requirements set out in PCT Rule 13.2 in that there is at least one "technical relationship" common among those claims. Specifically, the claims comprise the special technical feature of determining *tau* levels as part of a method for the early detection/diagnosis of the types of CNS damage recited in the claims. This "special technical feature" is not disclosed or suggested by